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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/575,932

12/26/2006

Anjana Rao

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FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER

STEADMAN, DAVID J

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

03/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/575,932		RAO ET AL.	
	Examiner		Art Unit	
	David J. Steadman		1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-54 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

- [1]** Claims 1-54 are pending in the application.
- [2]** Applicant's preliminary amendment to the claims, filed on 4/14/06, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims. Claims 28 and 49 have been amended relative to the original claim listing.
- [3]** Applicant's preliminary amendments to the specification, filed on 4/16/06 and 12/26/06, are acknowledged.
- [4]** Receipt of information disclosure statements, filed on 12/26/06 and 2/22/08, is acknowledged.
- [5]** Receipt of a sequence listing in computer readable form (CRF), a paper copy thereof, a statement of their sameness, a statement that no new matter has been added to the specification by the paper copy of the sequence CRF, and a formal amendment to the specification, directing entry of the substitute sequence listing paper copy into the specification and all filed on 12/26/06, is acknowledged.
- [6]** Receipt of a Declaration under 37 CFR 1.63, filed on 12/26/06, is acknowledged.

Lack of Unity

- [7]** Lack of unity is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-13 and 39, drawn to the special technical feature of a first method of identifying an anergy modulating agent.

Group II, claim(s) 14-16 and 26-28, drawn to the special technical feature of a process of making an anergy modulating agent.

Group III, claim(s) 17-19, drawn to the special technical feature of a second method of identifying an anergy modulating agent.

Group IV, claim(s) 20-25, drawn to the special technical feature of a third method of identifying an anergy modulating agent.

Group V, claim(s) 29-33, drawn to the special technical feature of a fourth method of identifying an anergy modulating agent.

Group VI, claim(s) 34-38, drawn to the special technical feature of a method of inhibiting anergy in a cell or patient.

Group VII, claim(s) 40, drawn to the special technical feature of a fifth method of identifying an anergy modulating agent.

Group VIII, claim(s) 41-45, drawn to the special technical feature of a sixth method of identifying an anergy modulating agent.

Group IX, claim(s) 46-48, drawn to the special technical feature of a seventh method of identifying an anergy modulating agent.

Group X, claim(s) 49, drawn to the special technical feature of an agent that modulates transcription of an E3 ubiquitin ligase gene.

Group XI, claim(s) 50-54, drawn to the special technical feature of a vector and a host cell.

[8] If applicant elects the invention of Group I, applicant is further required under PCT Rule 13.1 to elect one of the following ligase polypeptides:

- (A) Itch including SEQ ID NO:1 and 2
- (B) GRAIL including SEQ ID NO:11 and 12
- (C) Cbl including SEQ ID NO:5 and 6
- (D) Cbl-b including SEQ ID NO:7 and 8
- (E) Cbl-b3 including SEQ ID NO:9 and 10
- (F) Aip4
- (G) Nedd4 including SEQ ID NO:3 and 4

[9] If applicant elects the invention of Group I, applicant is further required under PCT Rule 13.1 to elect one of the following ligase substrate polypeptides:

- (H) PLC-gamma including SEQ ID NO:13 and 14
- (I) PKC-theta including SEQ ID NO:15 and 16
- (J) RasGAP including SEQ ID NO:17 and 18

[10] If applicant elects the invention of Group II, applicant is further required under PCT Rule 13.1 to elect one of the following polypeptides:

- | | | |
|-----------|---------------|---------------|
| (K) Itch | (L) Aip4 | (M) GRAIL |
| (N) Cbl | (O) Cbl-b | (P) Cbl-b3 |
| (Q) Nedd4 | (R) PLC-gamma | (S) PLC-theta |

[11] If applicant elects the invention of Group VI or IX, applicant is further required under PCT Rule 13.1 to elect one of the following polypeptides:

Art Unit: 1656

(T)	Itch	(U)	GRAIL	(V)	Cbl
(W)	Cbl-b	(X)	Cbl-b3	(Y)	AIP4
(Z)	Nedd4				

[12] If applicant elects the invention of Group XI, applicant is further required under PCT Rule 13.1 to elect one of the following ligase polypeptides:

- (AA) Itch including SEQ ID NO:1 and 2
- (BB) GRAIL including SEQ ID NO:11 and 12
- (CC) Cbl including SEQ ID NO:5 and 6
- (DD) Cbl-b including SEQ ID NO:7 and 8
- (EE) Cbl-b3 including SEQ ID NO:9 and 10
- (FF) Aip4
- (GG) Nedd4 including SEQ ID NO:3 and 4
- (HH) PLC-gamma including SEQ ID NO:13 and 14
- (II) PKC-theta including SEQ ID NO:15 and 16
- (JJ) RasGAP including SEQ ID NO:17 and 18

[13] The technical feature linking groups I-XI is an E3 ubiquitin ligase polypeptide.

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(B)(1) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a

Art Unit: 1656

common structure. Although the polypeptides of Groups (A) to (G), (H) to (J), (K) to (S), or (T) to (Z) or the vectors of Groups (AA) to (JJ) share a common property or activity, the compounds are not regarded as being of similar nature because all alternatives do not share a common structure.

According to PCT Rule 13.2 unity of invention exists only when the shared same or corresponding special technical feature is a contribution over the prior art. The inventions of Groups I-XI do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature of Groups I-XI is an E3 ubiquitin ligase polypeptide, which is shown by Berleth et al. (*J Biol Chem* 267:16403-16411, 1992; cited as reference C8 in the IDS filed on 8/15/07) to lack novelty or inventive step because the reference of Berleth et al. teaches an E3 ubiquitin ligase polypeptide and use thereof in identifying inhibitors of E3 ubiquitin ligase (see, e.g., p. 16404-16405) and does not make it a contribution over the prior art.

37 CFR 1.475 does not provide for the inclusion of multiple methods of use within the main invention. Accordingly, the methods of Groups II-IX do not have unity of invention with the method of Group I.

[14] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[15] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

[16] The claims will be examined only to the extent they read on the elected subject matter.

Notice of Possible Rejoinder

Art Unit: 1656

[17] The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

Art Unit: 1656

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Steadman/
David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656